DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

JUL 26 2007

The Honorable Joe L. Barton
Ranking Member
Committee on Energy and Commerce
House of Representatives
Washington, D.C. 20515-6115

Dear Mr. Barton:

Thank you for the letter of April 12, 2007, co-signed by Ed Whitfield, Ranking Member, Subcommittee on Oversight and Investigations. Your letter requests information on appeals of Warning Letters issued by the Food and Drug Administration (FDA or the Agency). Pursuant to an agreement with your staff, we are providing information related to warning letters issued by the Center for Devices and Radiological Health (CDRH).

We have restated your questions in bold followed by our response.

1. **For the last 10 years, how many warning letters have been appealed to the FDA? For all those cases, in how many instances has FDA ruled in favor of the company?**

FDA sends Warning Letters only for violations significant enough to support an enforcement action against a firm or other regulated entity. The Warning Letter provides the firm with a description of the violations and an opportunity to correct them. If a firm chooses not to correct the violations outlined in the Letter, the Agency would then have the option of initiating other enforcement actions as stated in the Warning Letter. While there is no formal appeal process specifically designated for Warning Letters, there are a variety of formal and informal processes through which regulated entities can request Agency review of a Warning Letter. The manner in which the Agency processes and responds to such requests varies depending on the nature of the request, the form in which it was submitted, and what, if any, procedural requirements govern the Agency's response. Requests for review of Warning Letters are usually resolved through informal processes, such as a regulatory meeting between the firm and personnel from the relevant FDA district office and/or Center. FDA does not maintain a centralized system to identify or track such requests, and the first step in locating this information would involve a complex, Agency-wide search encompassing all of FDA's district offices and CDRH to determine if any such information is available. We will, however, continue to work with your staff to identify specific requests of interest and provide that information to the extent possible.

2. **For the last 10 years, how many request for review by the FDA Commissioner pursuant to 21 C.F.R. 10.75 have been submitted? Is there a deadline for when the FDA responds on whether the request will be granted? If so, what is it? If so, why not? If there is no deadline, will FDA implement a 30-day deadline on the FDA to deny or grant a request for appeal? How many requests have been granted? How many requests have not been granted because of an intervening FDA enforcement action? How many requests have been granted and then mooted out because of an intervening FDA enforcement action? What are the criteria used by the FDA Commissioner to deny Appeals?**

FDA's administrative practices and procedures are set forth in Title 21, *Code of Federal Regulations* (CFR), Part 10. Part 10 provides several mechanisms to enable persons outside FDA to seek review of the Agency's decisions or actions. Section 10.75 allows persons outside the Agency to request informal review of an Agency action or decision through the established channels of supervision or review. Appeals of Agency actions or decisions under section 10.75 may be reviewed by the relevant Center Director or the Office of the Commissioner: to resolve a matter that cannot be resolved at lower levels within the Agency; to review policy matters requiring the attention of Center or Agency management; to address an unusual situation requiring immediate review in the public interest; or as required under the Agency's delegations of authority. It is, however, within the Commissioner's discretion whether to hear an appeal under 10.75(c).

There is no deadline for FDA to respond to requests for review under section 10.75, nor is an interested person required to file a section 10.75 request for review within a specified period of time following the Agency action or decision for which review is sought. FDA believes the informal processes described in section 10.75 provide maximum flexibility and openness for members of the public and the Agency and that in most cases, 30 days would be insufficient to allow the Commissioner, Center Director, or supervisory FDA official to acquire adequate familiarity with the regulatory and scientific considerations relevant to an action being appealed. FDA does not believe the interests of the public or the Agency would be best served by imposing a timeframe for review of section 10.75 requests that would preclude thorough review.

FDA does not maintain a uniform system of tracking or quantifying section 10.75 requests. The regulation, 21 C.F.R. § 10.35(d) states, however, that the administrative measures available under Part 10 will not stay an enforcement action. Therefore, the filing of a request for an appeal of a finding of statutory or regulatory violations under section 10.75 does not require FDA to stay an enforcement action pending the outcome of the appeal. This ensures that these administrative processes do not tie the Agency's hands indefinitely when the Agency believes violations of the law have occurred.

3. Can the FDA Commissioner delegate his authority to handle such appeals? If so, under what authority?

The delegations of authority from FDA's Commissioner to other FDA officials appear in FDA's Staff Manual Guide (SMG), which is available at: *www.fda.gov/smg/default.htm.* Under SMG 1410.21, eleven FDA officials, including the Associate Commissioner for External Relations, have been delegated all of the authorities of the Commissioner.

4. For the last 10 years, in how many cases has FDA imposed civil money penalties? Please list the cases including the name of the defendants, amount of penalties, date, a brief description of the basis for the penalties. Please include those cases that settled where FDA threatened to impose civil money penalties.

- ***Alko Diagnostic Corporation (Docket No. 1997H-001)*** - On January 2, 1997, Alko Diagnostic Corporation (Alko), Holliston, Massachusetts, entered into a settlement agreement in an administrative action for civil money penalties (CMP) involving the interstate distribution of fluid packs, reagent cartridges, diluents, and calibrators without 510(k) clearance. Under the terms of the agreement, the firm agreed to pay penalties of $130,000.

- ***Community Medical Imaging (Docket No. 1997H-0379)*** - On August 12, 1998, Community Medical Imaging, Inc. (CMI), Chicago, Illinois, along with the president and the supervising radiologist, entered into a settlement agreement in an administrative CMP action involving violations of the Mammography Quality Standards Act of 1992 (MQSA). The MQSA requires mammography facilities to maintain certifications demonstrating that the facilities comply with FDA's standards for clinical image quality and reliability. The violations were based on the firm continuing to perform mammography examinations without a valid certificate after being denied accreditation by the American College of Radiology for failing to meet quality standards. Under the agreement, CMI, and its president, Thomas Miller, jointly paid $25,000 in penalties and were prohibited from directly or indirectly owning or operating a mammography facility for a period of five years beginning August 12, 1998. The facility's supervising radiologist, Dr. Rudsen Bueser, paid $5,000 in penalties.

- ***Pure Water, Inc. (Docket No. 2000H-1436)*** - On November 20, 2000, Pure Water, Inc., Anderson, South Carolina, and two individuals, Ted M. Walters and Cynthia P. Walters, entered into a settlement agreement in an administrative CMP action involving the interstate shipment of an unapproved reverse osmosis water purification system for hemodialysis. Under the terms of the agreement, the firm and individuals agreed to pay $55,000 in penalties.

- ***LaserVision Centers, Inc. (Docket No. 2000H-1242)*** - On January 12, 2001, LaserVision Centers, Inc., St. Louis, Missouri, and four of its executives entered into a settlement agreement in an administrative CMP action involving the interstate shipment of unapproved excimer lasers used to treat nearsightedness. The violations were based on unapproved changes to the operating software for the firm's approved devices. Under the terms of the settlement agreement, the firm agreed to pay penalties of $1,000,000 and the four

individuals, including the firm's President and General Counsel, agreed to a total penalty of $500,000 with joint and several liability.

- ***World Wide Medical (Docket No. 2001H-0065)*** - In March, 2001, Worldwide Medical Corporation, and three individuals entered into a settlement agreement in an administrative CMP action involving the illegal sale of drug abuse test kits. Under the terms of the agreement, the firm and the original President/CEO agreed to pay penalties of $150,000 plus interest. The firm filed for Chapter 11 bankruptcy after making only one payment.

- ***Korangy Radiology Associates, P.A., t/a Baltimore Imaging Centers (Docket No. 2003H-0432)*** - On September 22, 2003, FDA filed an administrative Complaint for CMPs against Dr. Amile Korangy and Korangy Radiology Associates, P.A. (KRA), trading as Baltimore Imaging Centers, for violations of the MQSA. On May 27, 2004, the Administrative Law Judge (ALJ) granted FDA's motion for partial summary judgment on the issue of liability, finding that Respondents Korangy and KRA were each liable for 193 violations of the MQSA – one each for failing to obtain a certificate to perform mammography services as required by the MQSA, and 192 each for mammograms performed without a certificate. Thereafter, the ALJ held a hearing on penalty amount and in December 2004 issued a decision imposing CMPs of $3,000 per violation per Respondent, for a total CMP of $1,158,000.00. The Respondents appealed the ALJ's decision to the Department of Health and Human Services Departmental Appeals Board (DAB). On September 26, 2005, the DAB issued a decision upholding in its entirety the ALJ's decision. On November 17, 2005, Respondents appealed the DAB's decision to the United States Court of Appeals for the Fourth Circuit Court. Oral arguments before the Fourth Circuit were held in May 2007.

- ***LaHaye Center for Advanced Eye Care (Docket # 2002H-0443)*** - On November 5, 2003, LaHaye Center for Advanced Eye Care, Lafayette, Louisiana, and Leon C. LaHaye, M.D., entered into a settlement agreement in an administrative CMP action involving violations of the Investigational Device Exemption (IDE) requirements for an investigational laser device. The violations were based on the Respondents' use of an investigational laser device under conditions which failed to meet IDE requirements and their submission of false data to the FDA to support product approval. Under the terms of the agreement, Dr. LaHaye agreed to pay penalties of $150,000 and the corporation agreed to pay $950,000. Dr. LaHaye also was disqualified from conducting clinical studies.

- ***Ecumed Health Group Facility (Docket No. 2004H-0322)*** - On July 19, 2004, FDA filed an administrative Complaint for CMPs against Ecumed Health Group Facility, Hialeah, Florida and Amador Reyes, Owner/President, Juan C. Carrai, former Vice President; Dr. Richard Stone, a Radiologist; and Dr. Erlinda Enriquez, a Radiologist, based on violations of the MQSA. The violations in this case were based on 1,201 mammography examinations conducted by Ecumed during the 299 days in which it was uncertified. The Agency entered into settlement agreements with Mr. Carrai ($8,000), Dr. Stone ($95,000), and Dr. Enriquez ($92,400) based on the mammography examinations they conducted while the facility was uncertified. The firm and its president continued to litigate the claims against them for several months, but then failed to appear at a hearing scheduled by the ALJ. Subsequently, the firm and Mr. Reyes were ordered to pay penalties of $150,000 each.

- ***Gerald O. Dorros, M.D. (Docket No. 2005H-0099)*** - On March 1, 2005, Gerald O. Dorros, M.D., entered into a settlement agreement in an administrative CMP action involving the interstate shipment of unapproved medical devices. Under the terms of the agreement, Dr. Dorros agreed to pay $30,000 in penalties. Dr. Dorros was also indicted in a separate criminal action for making false statements to FDA and to United States Customs and Border Protection regarding the illegal importation of unapproved devices and using unapproved medical devices to conduct research on patients without notifying or obtaining the approval of FDA. On June 6, 2005, Dr. Dorros was sentenced to two (2) years probation, and a $5,000 fine. He also was fined $1,065,000 for making false claims.

- ***TMJ Implants (Docket No. 2005H-0271)*** - On July 14, 2005, FDA filed an administrative Complaint for CMPs against TMJ Implants, Inc., and two individuals, Robert Christensen and Maureen Mooney, based on their failure to file Medical Device Reports (MDRs) for adverse event reports which reasonably suggest that the firm's temporomandibular joint implant devices may have caused or contributed to serious injuries. FDA is seeking CMPs in the amount of $170,000 ($10,000 per violation) against each Respondent. The Respondents have denied liability for the violations. A hearing for the purpose of cross-examination was held on April 16, 2007. On July 6, 2007, the ALJ entered an order finding the firm and individuals liable for 17 violations of the MDR requirements. The ALJ has stayed the assessment of penalties against the Respondents pending review of the Respondents' financial information and further briefing from both FDA and the Respondents on penalty amounts.

Thank you again for contacting us about this matter. If we can answer further questions or provide additional information, please let us know. A similar response is being sent to Ranking Member Whitfield.

Sincerely,

Michael Nital

for Stephen R. Mason
Acting Assistant Commissioner
for Legislation